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OGUNBIYI, OLUWATOSIN A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,020	DELAGRAVE, SIMON	
	Examiner	Art Unit	
	Oluwatosin Ogunbiyi	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) 1-17 and 19-23 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 18 is/are rejected.

7)☒ Claim(s) 18 is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/5/07.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are pending in the application. Claim 18 is under examination. Claims 1-17 and 19-23 are withdrawn.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I: claims 1-12 drawn to a polypeptide comprising an engineered PDZ domain, wherein said engineered PDZ domain binds to a target associated with a pathogen or disease state.

Group II: claims 13-15 drawn to a polynucleotide encoding a polypeptide comprising an engineered PDZ domain, wherein said engineered PDZ domain binds to a target associated with a pathogen or disease state.

Group III: claims 16, drawn to an antibody that binds to a polypeptide comprising an engineered PDZ domain, wherein said engineered PDZ domain binds to a target associated with a pathogen or disease state.

Group IV: claim 17, drawn to a method of detecting the presence of a pathogen or disease in a patient comprising: a) administering a polypeptide comprising an engineered PDZ domain, wherein said engineered PDZ domain binds to a target associated with a pathogen or disease state to said patient; and b) detecting binding of said polypeptide in said patient.

Group V: claim 18, drawn to a method of detecting the presence of a pathogen or disease in a sample comprising: a) contacting a polypeptide comprising an engineered PDZ domain, wherein said engineered PDZ domain binds to a target associated with a pathogen or disease state with said sample; and b) detecting binding of said polypeptide to said sample.

Group VI: claim 19 and 23 drawn to a method of preparing a polypeptide comprising a PDZ domain, wherein said PDZ domain binds to a target produced by a pathogen or disease state, comprising: a) creating a library of polypeptides from one or more parent polypeptides comprising a PDZ domain; b) identifying one or more polypeptides from said library having binding affinity for said target.

Group VII: claim 20-22, drawn to a method of treating a disease, comprising administering to a patient afflicted with or likely to be afflicted with said disease a therapeutically effective amount of a polypeptide comprising a PDZ domain capable of binding to a target associated with said disease.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

1. The technical feature of Group I is a polypeptide comprising an engineered PDZ domain, wherein said engineered PDZ domain binds to a target associated with a pathogen or disease state. The technical feature of Group II are the polynucleotide having a nucleotide sequence chosen from one of SEQ ID NO: 33 through SEQ ID NO: 64.

2. The technical feature of Group II is a polynucleotide encoding a polypeptide comprising an engineered PDZ domain, wherein said engineered PDZ domain binds to a target associated with a pathogen or disease state.

3. The technical feature of Group III is an antibody that binds to a polypeptide comprising an engineered PDZ domain, wherein said engineered PDZ domain binds to a target associated with a pathogen or disease state.

4. The technical feature of Group IV is the method of detecting the presence of a pathogen or disease in a patient comprising: a) administering a polypeptide comprising an engineered PDZ domain, wherein said engineered PDZ domain binds to a target associated with a pathogen or disease state to said patient; and b) detecting binding of said polypeptide in said patient.

5. The technical feature of Group V is the method of detecting the presence of a pathogen or disease in a sample comprising: a) contacting a polypeptide comprising an engineered PDZ domain, wherein said engineered PDZ domain binds to a target associated with a pathogen or disease state with said sample; and b) detecting binding of said polypeptide to said sample.

6. The technical feature of Group VI is the method of preparing a polypeptide comprising a PDZ domain, wherein said PDZ domain binds to a target produced by a pathogen or disease state, comprising: a) creating a library of polypeptides from one or more parent polypeptides comprising a PDZ domain; b) identifying one or more polypeptides from said library having binding affinity for said target.

7. The technical feature of Group VII is the method of treating a disease, comprising administering to a patient afflicted with or likely to be afflicted with said disease a therapeutically effective amount of a polypeptide comprising a PDZ domain capable of binding to a target associated with said disease.

The technical feature of Group I is anticipated by the art and therefore not special within the meaning of PCT Rule 13.2 because it does not provide for a contribution that the claimed invention makes over the art. Junqueira et al (Oncogene, 2003 22:2772-2781) teaches a polypeptide comprising an engineered PDZ domain (PDZomi domain randomly mutated), wherein said engineered PDZ domain binds to a Myc protein said Myc being a proto-oncogene associated with cancer.

Species election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are as follows:

Invention I

Species of pathogen selected from: Bacillus anthracis, Clostridium botulinum, viral or fungal

Invention VII

Species of pathogen selected from: Bacillus anthracis, Clostridium botulinum, Clostridium tetani

The following claims are generic and deemed to correspond to the species listed above in the following manner:

1. Claims 1,5-12 (Group I)
2. Claims 20 and 21 (Group II)

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: technical feature linking species is not novel and is not defined over the prior art. Furthermore, the species of Bacillus anthracis is known in the art (Andersen et al. Journal of Bacteriology, Jan 1996, p. 377-384) and therefore does not define a special technical feature.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant's Election of an Invention

During a telephone conversation with Ms. Christine Goddard on 12/12/07 a provisional election was made without traverse to prosecute the invention of Group V, claims 18.

Affirmation of this election must be made by applicant in replying to this Office action.

Claims 1-17, 19-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention and species.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Drawings

The drawings in this application have been accepted. No further action by Applicant is required.

Information Disclosure Statement

The information disclosure statement filed 3/5/07 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because:

Copies of an English translation of the lined through foreign documents or portions thereof are not filed. Also copies of Ferrer et al 2002 Anal Biochem, 301: 207-16 and Tatiana A Tatusova et al (1999) have not been submitted.

Other references have been considered but the information referred to therein in the missing documents has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Objections

Claim 18 is objected to because the claim is dependent on a non-elected claim i.e. claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn to a method of detecting the presence of a disease in a sample comprising: a) contacting a polypeptide comprising an engineered PDZ domain with said sample; and b) detecting binding of said polypeptide to said sample.

The claim requires a polypeptide comprising an engineered PDZ domain. Said engineered PDZ domain binds to target associated with any pathogen or any disease state.

The specification defines an "engineered" PDZ domain as non-naturally occurring, such as a PDZ domain whose properties, including sequence, have been changed by in vitro mutation according to any suitable method including rational design or directed evolution. The engineered polypeptide typically has properties that differ from a naturally occurring polypeptide, such as different binding specificity or affinity.

Thus, the genus of polypeptides comprising an engineered PDZ domain is large and comprises structurally variant species due to, for example, a plethora of possible mutations that can be introduced into the PDZ domain sequence.

There are no sufficient identifying characteristics of the genus of said species of polypeptides comprising an engineered PDZ domain. Said species are described only by a functional characteristic without any known or disclosed correlation between the biological function and structural characteristics. *In re Bell* F.2d 781, 26 USPQ2d (Fed. Cir 1993).

The specification fails to teach the common structure of the numerous possibilities of polypeptides comprising an engineered PDZ domain that binds to a target associated with a pathogen or a disease state. The specification discloses that variants (generated by mutation) of hCASK PDZ domain and human Dlg1 are screened for binding to a Botulinum toxin peptide or a *Bacillus anthracis* peptide (

example 21 p. 36 and example 22 p.37). However, the specification does not teach the common structure of these and other species of polypeptides comprising an engineered PDZ domain that function to bind to a target associated with any pathogen or any disease state.

The specification does not provide sufficient description for the large and variant genus of polypeptides comprising an engineered PDZ domain and one of skill in the art would not recognize that Applicant had possession of said genus that functions as claimed.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a method of detecting the presence of a disease in a sample comprising: a) contacting a polypeptide comprising an engineered PDZ domain with said sample; and b) detecting binding of said polypeptide to said sample.

The claim is confusing as to the detection of the presence of disease in a sample. Disease is defined in the dictionary as a disorder of structure or function in a human, animal or plant, especially one that produces specific symptoms (See compact Oxford English dictionary definition). In view of the above definition and the method steps in the claim, it is unclear how the presence of disease in a sample can be detected as disease is a state that is present in an organism not a sample. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 18 is rejected under 35 U.S.C. 102(a) as being anticipated by Junqueira et al (Oncogene, May 8, 2003 22:2772-2781).

The claim is drawn to a method of detecting the presence of a disease in a sample comprising: a) contacting a polypeptide comprising an engineered PDZ domain with said sample; and b) detecting binding of said polypeptide to said sample.

Junqueira et al teaches a method of detecting the presence of a Myc protein said Myc being a proto-oncogene associated with cancer comprising contacting a polypeptide comprising an engineered PDZ domain (PDZomi domain randomly mutated thus is engineered) with a sample comprising said Myc protein wherein said engineered PDZ domain binds to said Myc protein and detecting said binding (see abstract, see table 1 p. 2775).

Claim 18 is rejected under 35 U.S.C. 102(e) as being anticipated by Lu et al. US2004/0018487 published Jan. 29, 2004 filed Jul. 29, 2003 with priority to provisional application 60/409,298.

The claim is drawn to a method of detecting the presence of a pathogen or disease in a sample comprising: a) contacting a polypeptide comprising an engineered PDZ domain with said sample; and b) detecting binding of said polypeptide to said sample.

Lu et al teaches a method of detecting the presence of oncogenic human papillomavirus (p. 37 paragraph 307) thus the likelihood of cancer (p. 39 paragraph 327) in clinical samples obtained from a patient comprising contacting a polypeptide comprising an engineered PDZ domain i.e. PDZ domain variants engineered to contain amino acid substitutions (p.7 paragraph 71) and detecting binding of said polypeptide with said sample (see p. 9 paragraph 84, claims p. 157).

Status of the Claims

Claim 18 is rejected and not allowed.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-0855. The examiner can normally be reached on M-F 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Examiner Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Oluwatosin Ogunbiyi
Examiner
Art Unit 1645

PATRICIA A. DUFFY
PRIMARY EXAMINER